STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH
Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

September 4, 2019

Dawn Rudolph, Administrator
St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

Dear Ms. Rudolph:

Unannounced visits were made to St. Vincent's Medical Center commencing on August 15, 2019 and concluding on September 4, 2019 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits. The state violations cannot be edited by the provider in any way.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by September 14, 2019.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by September 14, 2019 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

A phone conference has been scheduled for September 25, 2019 at 10:00 A.M. in the Facility Licensing and Investigations

DATES OF VISIT: commenced on August 15, 2019 and concluded on September 4, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting. Please be prepared to discuss those violations identified with an asterisk.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, R.N., B.S.
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:lst

CT #'s 25594, 25680, 24057, 23886, 23878, 23779, 23213, 23051, 24965

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THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6).

1. Based on medical record review, review of facility policy and interviews, the facility failed to ensure that nutritional recommendations were followed. The finding includes:
   a. Patient (P) #5. A 101 year old with a history of congestive heart failure (CHF), chronic kidney disease, right pleural effusion, and diet controlled diabetes was admitted to the hospital on 12/15/18 with recurrent right pleural effusion after a right thoracentesis was performed in the Emergency Department (ED) on 12/15/18.

      Physician orders dated 12/15/18 directed P#5 to receive a puree diet. A nutritional consult dated 12/18/18 noted that P #5 was malnourished, recommended to discontinue the pureed diet restriction and add Ensure twice a day to his/her diet. The medical record lacked documentation that the dietary recommendations were addressed by the Medical Doctor (MD) at this time.

      Physician orders dated 12/18/18 at 11:59 PM directed P#5 be NPO (nothing by mouth) except for medications. A routine order was placed by MD #2 for a right lung PleurX catheter insertion, to be performed in interventional radiology (IR), on 12/19/18 at 12:03 PM.

      IR documentation and/or physician progress notes dated 12/19/18 and 12/20/18 indicated that the IR procedure was unable to be performed.

      Medical emergency treatment documentation dated 12/21/18 identified, in part, that P #5's blood sugar was 44 mg/dl (very low) at 11:24 AM. Dextrose was administered and P #5's blood sugar rose to 197 mg/dl (above normal) at 11:30 AM.

      Review of P #5's EMR (electronic medical record) with Registered Nurse (RN) #1 on 8/16/19 at 8:50 AM identified that P #5 remained NPO after the IR procedure was cancelled on 12/19/18 at 3:30 PM. Further review of P #5's EMR with RN #1 identified that P #5 did not have a continuous fluid intravenous (IV), took fluids orally only with medications and his/her nutritional intake had not been documented after 12/16/18. According to the medical record a diet had been ordered for P#5 until 12/20/18 at 4:30 PM.

      The facility failed to ensure the patient's nutritional needs were met.

      The facility patient rights policy identified that the patient should expect, in part, considerate care at all times.

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2. Based on medical record review, review of facility policies and interviews for one of three patients reviewed for pain (P #4), the facility failed to follow pain medication orders and/or assess the patient's level of pain. The finding includes:
   a. Patient (P) #4 had a history of atrial fibrillation, coronary artery disease, and chronic obstructive pulmonary disease and was admitted to the hospital on 1/17/18 for an elective cardiac ablation procedure. A routine transseptal puncture was performed as part of the procedure by Medical Doctor (MD) #7. P #4 experienced severe substernal pain following the procedure and required pain medication administration.

      During a review of P #4's electronic medical record (EMR) with Registered Nurse (RN) #1 on 8/16/19 identified the following:

      i. MD orders directed administration of Dilaudid every 10 minutes intravenous push (IVP) 0.2 milligrams (mg) for a pain level of 4-5, 0.3mg for a 6-7 pain level and 0.4mg for a pain level of 8-10, to a maximum dose of 2mg. P#4 received Dilaudid 0.4mg and 0.2mg on 1/17/18 at 1:46 PM and 3:15 PM respectively for a pain level of 6, instead of the ordered Dilaudid 0.3mg for a pain level of 6-7.
      ii. P #4 received Percocet orally on 1/18/18 at 9:12 AM and 2:08 PM however assessments of P #4's pain level before and after each medication was not documented.
      iii. On 1/19/18 at 12:00 AM P #4 reported a pain level of "9" and although P #4 received Aspirin, IVP Morphine, Dilaudid and Percocet for pain on 1/19/18 between 1:23 AM and 12:33 PM the medical record lacked pain assessments before and after the pain medications were administered.

   The facility Pain Management policy identified that at a minimum, pain will be assessed once every shift, during therapy sessions and 30 to 60 minutes post administration of as needed pain medications. The policy further directed that opioids- analgesics are titrated to a level of pain relief.

   The facility patient rights policy identified that the patient has the right to have his/her pain managed.

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3. *Based on clinical record review, review of facility documentation, review of facility policy, and interviews for one of three sampled patients (Patient #6) reviewed for surgical procedures, the facility failed to ensure a surgical sponge was not retained following a surgical procedure. The findings include:
   a. Patient #6 was admitted to the hospital on 7/20/18 for a scheduled whipple procedure for pancreatic cancer.

      The intraoperative report dated 7/30/18 identified sponges, instruments and sharps were counted at 7:30 AM, 11:10 AM, 3:04 PM, and a final count was done at 5:01 PM. All counts were identified as correct. The procedure stop time was 5:14 PM.

      The X-Ray report dated 7/30/18 at 7:41PM identified a radiopaque structure projecting over the right upper quadrant.

      The operative report dated 7/30/18 at 11:30 PM identified the patient was taken back to the OR at 9:00 PM for an exploratory laparotomy and foreign body removal. The presence of the sponge was confirmed with the RF wand, the incision was opened, and a lap pad (sponge) was removed from the right upper quadrant.

      Interview and review of hospital documentation with the Clinical Director of Surgical Services on 8/15/19 at 11:00 AM identified RN #3 and RN #4 did a verbal count instead of a manual count at 3:04 PM at change of shift on 7/30/19 when RN #4 relieved RN #3 as the circulator. The clinical director identified RN #4 scanned the patient with the RF wand to detect for retained sponges upon the completion of surgery but none were found. When the patient was taken back to the OR and rescanned with the RF wand the sponge was detected on 2 out of 3 attempts. She identified the RF wand was temporarily taken out of service but testing of the RF wand identified it was functioning appropriately and returned. The clinical director further identified although an x-ray was done after the surgery was completed, it was to check for placement of a central line and the sponge was an incidental finding. She identified because the surgery was greater than eight hours, per hospital policy an x-ray should have been done prior to completion.

      Interview with RN #3 on 8/15/19 at 11:38 AM identified on 7/30/18 when RN #4 joined the case at 3:00 PM, they did a manual count of the sponges, instruments, and sharps. RN #3 identified RN #4 relieved her as the circulator, and she became the scrub nurse. RN #3 further identified she did another count with RN #4 at the end of the surgery, and all counts were correct. RN #4 identified it was a long, complex case and she cannot account for

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where the retained sponge came from because all of the counts were correct. Interview with RN #4 on 8/15/19 at 2:15 PM identified she cannot recall if she did or did not manually count the sponges with RN #3 on 7/30/18 when he/she relieved her. RN #4 identified she scanned the patient with the RF wand upon completion of the surgery and it failed to identify the sponge.

Although, RN #4 identified the sponge count was done per hospital policy, the hospital investigation at the time of the incident identified the sponge count was not done per hospital policy and a sponge was retained.

The hospital policy for sponge, sharp, and instrument counts directs counts are taken before procedure begins, when any additional item is added, before wound closure begins, at skin closure, and at time of permanent relief of either scrub person and/or circulating nurse. The policy also directs an x-ray will be done if the case is over 8 hours.

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4. Based on clinical record reviews, review of facility documentation and interviews for one of three sampled patients (P#1) who were reviewed for fall risk and/or falls, the facility failed to complete an accurate fall risk assessment. The findings include:
   a. P (Patient) # 1's diagnosis included degenerative arthritis, osteoporosis, diabetes, obesity, and re-current urinary tract infections (UTI). On 1/29/18 the patient was admitted for right total hip arthroplasty. (THA)

      A nurse's progress note dated 1/29/18 at 6:23 PM identified the patient was admitted to inpatient services status post THA with no complications. The P#1 was alert and oriented, denied pain, and ambulated with the assistance of two persons approximately thirty feet.

      Fall Risk Assessments conducted every shift from 1/29/18 to 2/2/18 identified P#1 scored a #3 on the Hendrich Fall Risk Scale. A #5 or greater on the scale would indicate the patient was at high risk for falls.

      On 1/30/18 at 7:25 PM P#1's temperature was 100.7 degrees Fahrenheit. The physician was notified and ordered blood cultures, and a urinalysis with culture and sensitivities. Subsequently P#1 was diagnosed with a UTI and antibiotics were initiated.

      A nurse's progress note dated 2/2/18 identified at 4:10 PM P#1 was found kneeling on the floor in the bathroom. The patient indicated his/her right knee buckled while ambulating to the bathroom. The patient complained of left knee and right hip discomfort. An X-ray report dated 2/2/18 identified an acute fracture of the lessor trochanter adjacent to the patient's recently placed right hip prosthesis. P#1 returned to surgery on 2/5/18 for open reduction with internal fixation (ORIF) with plating and wiring of the right femur.

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An Adverse Event Reporting Form dated 2/28/18 identified P#1 was having frequent urination related to a newly diagnosed UTI. The Hendrich Fall Risk Scale indicated frequent urination was identified in the criteria. Although P#1 did not meet the fall risk criteria initially scoring a #3 (not a fall risk), frequent urination/UTI had not been added to the score on the Hendrich fall risk scale therefore P#1's score would have increased to #4 (not a fall risk).

An interview on 8/15/19 at 11:15 AM with the Clinical Director of Surgical Services identified P#1's frequent urination and UTI should have been assessed as a contributing factor while evaluating the patient for fall risk resulting in P#1's fall risk score to be a #4 not a #3.

Review of the facility Corrective Action Plan (CAP) indicated to in order to prevent total joint replacement (TJR) patients from falls all TJR patients are considered at risk for falls for the duration of their hospital stay.